

Comments on ESE Alcohol Quality Assurance Project Plan

The review of the subject document prepared for ESE Alcohol, Inc. and dated January 2023 has been completed according to “EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations,” EPA QA/R-5 March 2001. The Sampling Plan was also provided and reviewed in terms of how it relates to and supports the QAPP.

Because the document was unsigned, it was reviewed as a draft and the comments are outlined below. Critical comments identify issues which need to be addressed before the document can be approved. General comments identify opportunities for strengthening the document but do not affect approval.

Critical Comments

1. Project Personnel Sheet. Once the QAPP is ready for final approval, it will need to be submitted with the appropriate signatures from the facility and the program (with names and titles listed for each approver of the QAPP).
2. § 1.2 Project Schedule, page 1. It appears this QAPP will be supported by multiple SAPs. Is the intent for this to be a long-term QAPP? If so, this QAPP needs to address the following:
 - a. The fact that this is a long-term QAPP.
 - b. The periodic review of the QAPP reviewed, preferably annually, to ensure it remains up to date.
 - c. The fact that the QAPP approval is valid for the project period or up to five years, whichever is less, at which time the QAPP will need to be resubmitted for review and approval if it will be used beyond this timeframe.
 - d. The use of SAPs to support the QAPP and the review and approval requirements for the SAPs and that any project outside the scope of this parent QAPP will require a separate, stand-alone QAPP.
3. § 1.4.2 Project QA Officer, page 3. The Project QA Officer needs to be identified by name here or on the approval page to help demonstrate they are independent from those responsible for generating the data.
4. § 1.5 Problem Definition/Background, page 6. The project includes determining if activities at the site have caused pesticides to be present in shallow soil at concentrations that exceed applicable human health and ecological screening criteria, but the QAPP does not provide the screening criteria values and the accompanying SAP simply refers to levels of ecological concern and commercial/workplace levels for human/mammal exposure. It is critical to specifically define these criteria to demonstrate the selected method by the chosen laboratory is sensitive enough to meet these levels.
5. §§ 1.7.2.1 and 4.3.3.1. The Relative Percent Difference (RPD) used for measuring precision and representativeness needs to be provided in the QAPP.
6. § 1.8.2 Laboratory Operations, page 8. Laboratory references including ISO certification for the contaminants of concern in the applicable matrices and the ability to analyze samples by the selected method at the needed sensitivity could not be verified at the time of the review.

7. § 2.2.1 Field Measurements, page 10. Field measurements, including visual observations and GPS coordinates, may be taken in conjunction with the sampling tasks
 - a. Use of the word “may” implies these measurements are optional. It is not clear how it will be determined if and when field measurements will be taken and who will make this decision.
 - b. The accompanying SAP states GPS coordinates and details of the sampling will be recorded for each composite sampling location which seems inconsistent with this section of the QAPP which appears to make these field measurements optional.
 - c. This section indicates SOPs for these measurements are included in the SAP. However, these referenced SOPs do not appear to be included in the SAP.
8. § 2.2.2 Sampling Procedures, page 10.
 - a. Although there is text within the SAP providing a general overview of sampling, this section indicates SOPs for sampling soil and biosolids are included in the SAP. However, these referenced SOPs do not appear to be included in the SAP.
 - b. Appendix B is referenced for sample container, holding time and preservation requirements which includes keeping samples cool to 6°C. However, Section 2.4.3.1 indicates a temperature of up to 10°C. Is this meant to indicate an acceptable range of 6°C ($\pm 4^\circ\text{C}$)? SW-846 recommends keeping samples cool to 0-6°C. These preservation requirements need to be verified and the QAPP updated accordingly.
9. § 2.2.3 Cleaning and Decontamination of Equipment/Sample Containers, page 10. This section states SOPs for equipment decontamination are included in the SAP. However, these reference SOPs do not appear to be included in the SAP.
10. § 2.4.2 Sample Labeling, page 11. The SAP is referenced for details on sample labeling including unique sample identifications. However, this information could not be found in the QAPP. See also Section 2.4.3.1 which includes reference to the SAP for the sample numbering system.
11. § 2.4.3.1 Field Custody Procedures. The QAPP states that the samples will be stored at 10°C. However, the *Sample Container, Preservation and Holding Time Requirements and Analytical Methodologies* provided in Appendix B state that the samples should be stored at 6°C. Please revise.
12. § 2.5 Analytical Methods, page 13. This section indicates sample analysis is not limited to the laboratory listed. If another laboratory is used, it must be verified that laboratory can perform the required method at the needed sensitivity under the same certification and has equivalent methods and procedures to help ensure any data generated by different laboratories are comparable.
13. § 2.6.3 Laboratory Instrument Preventive Maintenance, page 14. This section focuses only on laboratory instruments but needs to also address any relevant information for the field or indicate it is not applicable. See also Section 2.7.

14. § 2.10 Data Management, page 15. This section identifies the components that make up data management but does not include how any of the data management components listed are applicable to this project and how they are being addressed.
15. § 4.2.3 Validation of Analytical Deliverables, page 20. Because data validation is a critical piece of the overall data usability review, it is not clear what is meant by “if” validation is performed on a particular data set. How it will be determined when validation will occur on which dataset(s) needs to be clarified as well as who will make this decision.
16. Appendix A. The reporting limit for ipconazole (10 µg/kg) is not adequate to meet the Data Quality Objectives (DQOs) of the study since the ecological level of concern is 0.3 to 5 µg/kg. Lower reporting limits are required.

General Comments

17. § 1.4 Project/Task Organization, page 2. It would be useful to also include EPA personnel and to summarize their project related responsibilities here.
18. § 1.1.1 QAPP Update/Modification, page 1. The process for ensuring that the most current approved version of the QAPP is available is described but it is not clear who has this responsibility.
19. § 1.9 Documents and Records, page 8. If a separate field narrative will be prepared to describe field activities including any problems identified in the field, it should be addressed here.
20. § 2.2.2 Sampling Methods Requirements, page 10. This section of a QAPP should include an equipment list or provide a reference to where this information can be found.
21. § 3.2 Reports to Management, page 18.
 - a. Will there be any routine project status reports prepared during this project? If so, they should be summarized here.
 - b. This section should also identify the preparer(s) and recipient(s) of reports.
22. § 4.3 Usability/Reconciliation with Data Quality Objectives, page 21.
 - a. If there will be any statistical analyses of the data in addition to calculation of the basis statistics for precision, accuracy, and completeness, it should be summarized here.
 - b. If any limitations on the use of the data are identified, how will they be reported to data users?